



## General

### Guideline Title

Use of hormonal contraception in women with coexisting medical conditions.

## Bibliographic Source(s)

American College of Obstetricians and Gynecologists (ACOG). Use of hormonal contraception in women with coexisting medical conditions. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2006 Jun. 20 p. (ACOG practice bulletin; no. 73). [179 references]

#### Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American College of Obstetricians and Gynecologists (ACOG). The use of hormonal contraception in women with coexisting medical conditions. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2000 Jul. 14 p. (ACOG practice bulletin; no. 18).

The American College of Obstetricians and Gynecologists (ACOG) reaffirmed the currency of the guideline in 2013.

## Recommendations

# Major Recommendations

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of "Major Recommendations."

The following recommendations are based on good and consistent scientific evidence (Level A):

A history of benign breast disease or a positive family history of breast cancer should not be regarded as contraindications to oral contraceptive use.

Combination oral contraceptives are safe for women with mild lupus who do not have antiphospholipid antibodies.

Combination contraceptives are not recommended for women with a documented history of unexplained venous thromboembolism or venous thromboembolism associated with pregnancy or exogenous estrogen use, unless they are taking anticoagulants.

Combination oral contraceptives should be prescribed with caution, if ever, to women who are older than 35 years and are smokers.

Use of the levonorgestrel intrauterine system is appropriate for women with diabetes without retinopathy, nephropathy, or other vascular

complications.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

Healthy, nonsmoking women doing well on a combination contraceptive can continue their method until the ages of 50 to 55 years, after weighing the risks and benefits.

Progestin-only oral contraceptives and depot medroxyprogesterone (DMPA) can be initiated safely at 6 weeks postpartum in lactating women and immediately postpartum in nonbreastfeeding women.

Combination contraceptives are not recommended as the first choice for breastfeeding women because of the possible negative impact of contraceptive doses of estrogen on lactation. However, use of combination contraceptives by well-nourished breastfeeding women does not appear to result in infant development problems; therefore, their use can be considered once milk flow is well established.

Women with well-controlled and monitored hypertension who are aged 35 years or younger are appropriate candidates for a trial of combination contraceptives, provided they are otherwise healthy, show no evidence of end-organ vascular disease, and do not smoke.

The use of combination contraceptives by women with diabetes should be limited to such women who do not smoke, are younger than 35 years, and are otherwise healthy with no evidence of hypertension, nephropathy, retinopathy, or other vascular disease.

The use of combination contraceptives may be considered for women with migraine headaches if they do not have focal neurologic signs, do not smoke, are otherwise healthy, and are younger than 35 years. Although cerebrovascular events rarely occur among women with migraines who use combination oral contraceptives, the impact of a stroke is so devastating that clinicians should consider the use of progestin-only, intrauterine, or barrier contraceptives in this setting.

Because of the increased risk of venous thrombotic embolism, combination contraceptives should be used with caution in women older than 35 years who are obese.

In women with depressive disorders, symptoms do not appear to worsen with use of hormonal methods of contraception.

If oral contraceptives are continued before major surgery, heparin prophylaxis should be considered.

The following recommendations are based primarily on consensus and expert opinion (Level C):

Most women with controlled dyslipidemia can use combination oral contraceptives formulated with 35 micrograms or less of estrogen. In women with uncontrolled low-density lipoprotein (LDL) cholesterol greater than 160 mg/dL, a triglyceride level greater than 250 mg/dL, or multiple additional risk factors for coronary artery disease, alternative contraceptives should be considered.

DMPA has noncontraceptive benefits and is appropriate for women with sickle cell disease.

Progestin-only contraceptives may be appropriate for women with coronary artery disease, congestive heart failure, or cerebrovascular disease. However, combination oral contraceptives are contraindicated in these women.

Short- or long-term use of DMPA in healthy women should not be considered an indication for dual-energy X-ray absorptiometry (DXA) or other tests that assess bone mineral density. In adolescents, the advantages of DMPA likely outweigh the theoretical safety concerns regarding bone mineral density and fractures. However, in the absence of long-term data in this population, consideration of long-term use should be individualized.

#### <u>Definitions</u>:

#### Grades of Evidence

I: Evidence obtained from at least one properly designed randomized controlled trial.

II-1: Evidence obtained from well-designed controlled trials without randomization.

II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

#### Levels of Recommendations

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

# Clinical Algorithm(s)

# Scope

## Disease/Condition(s)

Unintended pregnancy

## **Guideline Category**

Assessment of Therapeutic Effectiveness

Counseling

Risk Assessment

Treatment

# Clinical Specialty

Family Practice

Obstetrics and Gynecology

## **Intended Users**

Advanced Practice Nurses

Physicians

# Guideline Objective(s)

To aid practitioners in making decisions about appropriate obstetric and gynecologic care

To help clinicians and women with coexisting medical conditions make sound decisions regarding the selection and appropriateness of various hormonal contraceptives, including the levonorgestrel intrauterine system

# **Target Population**

Women of reproductive capability who have one or more of the following coexisting medical conditions or risk factors:

Age older than 35 years

Tobacco smoking

Hypertension

Lipid disorders

Diabetes

Migraine headaches

Fibrocystic breast changes, fibroadenoma, or family history of breast cancer BRCA1 or BRCA2

Uterine leiomyomata

Breastfeeding postpartum

Concomitant medications

Scheduled for surgery

History of venous thromboembolism (VTE)

Hypercoagulable conditions
Anticoagulation therapy
Obesity
Systemic lunus on themselves

Systemic lupus erythematosus (SLE)

Sickle cell disease

Depression

Human immunodeficiency virus (HIV) (acquisition, transmission, and progression)

### **Interventions and Practices Considered**

Combination oral contraceptives and combination contraception by transdermal and vaginal ring systems

Other forms of contraception, including progestin-only oral contraceptives (depot medroxyprogesterone acetate [DMPA] injections, progestin-only pills, and the levonorgestrel intrauterine system) and implants for women with contraindications to combination oral contraceptives

## Major Outcomes Considered

Effectiveness of contraception Patient morbidity

# Methodology

### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

# Description of Methods Used to Collect/Select the Evidence

2006 Original Guideline

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' (ACOG's) own internal resources and documents were used to conduct a literature search to locate relevant articles published between July 1971 and February 2006. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and ACOG were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

2013 Reaffirmation

The NCBI database was searched from 2006 to 2013. Committee members conducted a literature search with the assistance from the ACOG Resource Center staff who routinely perform the Practice Bulletin literature searches.

### Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

## Rating Scheme for the Strength of the Evidence

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force.

- I: Evidence obtained from at least one properly designed randomized controlled trial.
- II-1: Evidence obtained from well-designed controlled trials without randomization.
- II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
- II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

## Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

## Description of the Methods Used to Analyze the Evidence

Not stated

### Methods Used to Formulate the Recommendations

**Expert Consensus** 

# Description of Methods Used to Formulate the Recommendations

2006 Original Guideline

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

2013 Reaffirmation

The Committee on Practice Bulletins - Gynecology met in October 2013 and reaffirmed this document. A committee member reviewed the document and new literature on the topic. The document was then reviewed by the committee and the committee agreed that it is current and accurate.

# Rating Scheme for the Strength of the Recommendations

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

### Method of Guideline Validation

Internal Peer Review

## Description of Method of Guideline Validation

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and subspecialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

# **Evidence Supporting the Recommendations**

## Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

# Benefits/Harms of Implementing the Guideline Recommendations

### **Potential Benefits**

Appropriate use of hormonal contraception in women with coexisting medical conditions

Benefits for Specific Populations

Perimenopausal women may benefit from a positive effect on bone mineral density and a reduction in vasomotor symptoms offered by combination oral contraceptives.

The reduced risk of endometrial and ovarian cancers associated with oral contraceptive use is of particular importance to older women of reproductive age.

Because oral contraceptive use reduces ovarian cancer risk in *BRCA1* and *BRCA2* carriers, as it does in noncarriers, use of oral contraceptives offers important benefits for women with *BRCA1* or *BRCA2* mutations.

Several large epidemiologic studies have observed that oral contraceptive use does not induce the growth of uterine leiomyomata and may decrease bleeding disorders in women with menorrhagia or dysmenorrhea associated with uterine leiomyomata.

Progestin-only pills and depot medroxyprogesterone acetate (DMPA) do not impair lactation and, in fact, may increase the quality and duration of lactation.

Two controlled studies assessing the use of DMPA in women with sickle cell disease found that the use of DMPA reduced the incidence of painful crises.

### Potential Harms

Combination contraceptives are not recommended for women with a documented history of unexplained venous thromboembolism or venous thromboembolism associated with pregnancy or exogenous estrogen use, unless they are taking anticoagulants.

Combination oral contraceptives should be prescribed with caution, if ever, to women who are older than 35 years and are smokers.

Combination oral contraceptives are not recommended as the first choice for breastfeeding women because of the possible negative impact of contraceptive doses of estrogen on lactation.

Because of the increased risk of venous thrombotic embolism, combination contraceptives should be used with caution in women older than 35 years who are obese.

## Contraindications

### Contraindications

In women with the following conditions, use of progestin-only oral contraceptives, including depot medroxyprogesterone acetate, may be safer than combination oral, transdermal, or vaginal ring contraceptives. An intrauterine device also represents an appropriate contraceptive choice for women with these conditions.

Migraine headaches, especially those with focal neurologic signs

Cigarette smoking or obesity in women older than 35 years

History of thromboembolic disease

Hypertension in women with vascular disease or older than 35 years

Systemic lupus erythematosus with vascular disease, nephritis, or antiphospholipid antibodies

Less than 3 weeks postpartum\*

Hypertriglyceridemia

Coronary artery disease

Congestive heart failure

Cerebrovascular disease

# Qualifying Statements

## **Qualifying Statements**

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

# Implementation of the Guideline

# Description of Implementation Strategy

An implementation strategy was not provided.

# Implementation Tools

Audit Criteria/Indicators

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

<sup>\*</sup>Use of an intrauterine device may not be an appropriate contraceptive choice.

### **IOM Domain**

Effectiveness

Patient-centeredness

# Identifying Information and Availability

## Bibliographic Source(s)

American College of Obstetricians and Gynecologists (ACOG). Use of hormonal contraception in women with coexisting medical conditions. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2006 Jun. 20 p. (ACOG practice bulletin; no. 73). [179 references]

## Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2000 Jul (revised 2006 Jun; reaffirmed 2013)

## Guideline Developer(s)

American College of Obstetricians and Gynecologists - Medical Specialty Society

# Source(s) of Funding

American College of Obstetricians and Gynecologists (ACOG)

### Guideline Committee

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Gynecology

## Composition of Group That Authored the Guideline

Not stated

### Financial Disclosures/Conflicts of Interest

Not stated

### **Guideline Status**

This is the current release of the guideline.

This guideline updates a previous version: American College of Obstetricians and Gynecologists (ACOG). The use of hormonal contraception in women with coexisting medical conditions. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2000 Jul. 14 p.

(ACOG practice bulletin; no. 18).

The American College of Obstetricians and Gynecologists (ACOG) reaffirmed the currency of the guideline in 2013.

## Guideline Availability

Electronic copies: Not available at this time.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 933104, Atlanta, GA 31193-3104; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site

## Availability of Companion Documents

Proposed performance measures are included in the original guideline document.

### Patient Resources

None available

### **NGC Status**

This NGC summary was completed by ECRI on September 14, 2004. The information was verified by the guideline developer on December 8, 2004. This NGC summary was updated by ECRI Institute on August 2, 2007. The updated information was verified by the guideline developer on September 10, 2007. This summary was updated by ECRI Institute on February 4, 2008 following the new U.S. Food and Drug Administration advisory on Ortho Evra Contraceptive Transdermal Patch. This summary was updated by ECRI Institute on March 14, 2008 following the updated FDA advisory on heparin sodium injection. This summary was updated by ECRI Institute on July 27, 2010 following the FDA drug safety communication on Heparin. The currency of the guideline was reaffirmed by the developer in 2008 and this summary was updated by ECRI Institute on November 30, 2011. The currency of the guideline was reaffirmed by the developer in 2013 and this summary was updated by ECRI Institute on March 7, 2014.

# Copyright Statement

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

# Disclaimer

### NGC Disclaimer

The National Guideline Clearinghouseâ, ¢ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion-criteria.aspx.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.